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Philippines

Biotechnology

GM Commercialization Guidelines Approved

2002

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Report Highlights:
On April 3, 2002 Agriculture Secretary Leonardo Q. Montemayor signed Administrative Order No. 8 or the Rules and Regulations for the Importation and Release into the Environment of Plants and Plant Products Derived from the Use of Modern Biotechnology.

Includes PSD changes: No
Includes Trade Matrix: No
Unscheduled Report
Manila [RP1], RP

Administrative Order No.8 (AO 8) or the Rules and Regulations for the Importation and Release into the Environment of Plants and Plant Products Derived from the Use of Modern Biotechnology was signed by Agriculture Leonardo Q. Montemayor last April 3, 2002 after a successful presentation to President Gloria Macapagal-Arroyo and her Cabinet. AO 8 makes the Philippines the first country in Southeast Asia with commercialization guidelines for genetically engineered plants and plant products.

The guidelines recognize the potential benefits from the safe and responsible use of modern biotechnology in increasing yields and improving product quality as well as the reduction in the application of agricultural chemicals and other environmentally hazardous substances.

AO 8 likewise provides the country procedures on how to take advantage of this technology safely consistent with its agricultural modernization program without unduly disrupting existing trade. The guidelines ensure continued access for an estimated $400 million of US commodities and products containing GMOs. Furthermore, it makes possible the finalization of field testing and the commercial sale of Bt corn seed within the next year. The two US companies involved estimate sales of $5 million within three years.

With the approval of the guidelines, reorientation and strengthening of concerned regulatory agencies becomes critical. A transition period of until June 30, 2002 is provided by AO 8 for the appropriate regulatory agencies to adjust to the new guidelines. The local Bureau of Plant Industry (BPI) shall, in general terms, be the agency responsible in administering AO 8.

Provided in the following pages is the full text of AO 8.

April 03, 2002

ADMINISTRATIVE ORDER NO. 8
Series of 2002

SUBJECT: RULES AND REGULATIONS FOR THE IMPORTATION AND RELEASE INTO THE ENVIRONMENT OF PLANTS AND PLANT PRODUCTS DERIVED FROM THE USE OF MODERN BIOTECHNOLOGY

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WHEREAS, it is the declared policy of the State to accelerate agricultural development and enhance the production of agricultural crops by optimizing the use of resources and applying modern farming systems and technology to attain food security for domestic use and to expand and diversify agricultural production for export;

WHEREAS, local agriculture can benefit from the safe and responsible use of modern biotechnology by opening the possibility of increasing the yield, improving the product quality, reducing the use of pesticides and other farm inputs, enhancing the integrity of the environment, and reducing the exposure of farmers and consumers to hazardous pesticide residues;

WHEREAS, the Government has recognized, as early as October 15, 1990, with the issuance of Executive Order No. 430, the potentials of modern biotechnology in improving the lives of the people;

WHEREAS, under Republic Act No. 8435, otherwise known as "The Agriculture and Fisheries Modernization Act of 1997", the Government has declared as one of its objectives the modernization of the agriculture sector by transforming it from a resource-based to a technology-based sector;

WHEREAS, on July 16, 2001, Her Excellency President Gloria Macapagal-Arroyo approved the Policy Statement on Modern Biotechnology, reiterating the government policy of promoting the safe and responsible use of modern biotechnology and its products as one of several means to achieve and sustain food security, equitable access to health services, sustainable and safe environment and industry development;

WHEREAS, the products of modern biotechnology cannot be enjoyed fully by the people unless uncertainties regarding their risks to human health and the environment are minimized and managed, if not eliminated;

WHEREAS, a responsive regulatory system is an essential component of the precautionary approach in dealing with the products of modern biotechnology;
WHEREAS, the Philippines, as a signatory to the Cartagena Protocol on Biosafety, is committed to ensuring that the development, handling, transport, use, transfer and release of genetically modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health;

WHEREAS, under Title IV, Chapter 4, Section 19 of the Administrative Code of 1987, the Department

of Agriculture, through the Bureau of Plant Industry, is responsible for the production of improved planting materials and protection of agricultural crops from pests and diseases; and

WHEREAS, there is a need to supplement the existing guidelines on the importation and release into the environment of the products of modern biotechnology by institutionalizing existing operational arrangements between the Bureau of Plant Industry and the National Committee on Biosafety of the Philippines and by providing regulations to govern the release of such products for propagation or for direct use as food or feed, or for processing;

NOW, THEREFORE, I, LEONARDO Q. MONTEMAYOR, Secretary of the Department of Agriculture, in accordance with the Consumer Act of the Philippines and Section 19, Chapter 4, Title IV, Book IV of Executive Order No. 292, Series of 1987, do hereby issue this Order governing the importation and release into the environment of plants and plant products derived from the use of modern biotechnology:

PART I
GENERAL PROVISIONS

Section 1
Definition of Terms

The following terms when used in this Administrative Order shall mean as follows, unless the context requires otherwise:

A. "Applicant" means the juridical person who, for the duration of the proposed activity, has control over the importation or release into the environment of a regulated article and shall ensure compliance with all the requirements in this Order and the conditions specified in the relevant permit. An applicant shall be: (i) any of the departments or agencies of the Philippine Government; (ii) a university-based research institution in the Philippines; (iii) an international research organization duly recognized by the Philippine government and based in the Philippines; (iv) a corporation registered with the Securities and Exchange Commission of the Philippines; or (v) a cooperative registered with the Cooperative Development Authority of the Philippines.

B. "BAFPS" means the Bureau of Agriculture and Fisheries Product Standards.

C. "BAI" means the Bureau of Animal Industry.

D. "BPI" means the Bureau of Plant Industry.

E. "Contained Use" means the use of a regulated article for research and development inside a physical containment facility intended to limit its contact with, and to provide for a high level of safety for, the general population and the environment and which has been inspected and approved by NCBP.

F. "Department" means the Department of Agriculture.

G. "Donor organism" means the organism from which genetic material is obtained for transfer to the

host organism.

H. "Environment" means any ecosystem or habitat that is likely to come into contact with a regulated article.

I. "Field testing" means any intentional introduction into the environment of a regulated article for purposes of research and development and for which no specific physical containment measures are used to limit the contact of the regulated article with, and to provide for a high level of safety for, the general population and the environment. Field testing may be conducted in a single site or in multiple sites.

J. "FPA" means the Fertilizer and Pesticide Authority.

K. "Host organism" means the plant which receives genetic material from a donor organism.

L. "IBC" means the Institutional Biosafety Committee established by an applicant in preparation for the field testing of a regulated article and whose membership has been approved by BPI. The IBC shall be responsible for the initial evaluation of the risk assessment and risk management strategies of the applicant for field testing. It shall be composed of at least five (5) members, three (3) of whom shall be designated as "scientist-members" who shall possess scientific and technological knowledge and expertise sufficient to enable them to evaluate and monitor properly any work of the applicant relating to the field testing of a regulated article. The other members, who shall be designated as "community representatives", shall not be affiliated with the applicant apart from being members of its IBC and shall be in a position to represent the interests of the communities where the field testing is to be conducted. For the avoidance of doubt, NCBP shall be responsible for approving the membership of the IBC for contained use of a regulated article.

M. "Importation" means the act of bringing into the Philippines a regulated article for use in research and development (whether for contained use or for field testing) or for release into the environment (whether for propagation or for direct use as food or feed, or for processing).

N. "Modern Biotechnology" means: (i) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation; (ii) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation; and (iii) cell fusion, including protoplast fusion, or hybridization techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

O. "NCBP" means the National Committee on Biosafety of the Philippines.

P. "Organism" means any entity able to replicate its own genetic material.

Q. "Permittee" means any applicant who has been granted by BPI a permit to import or to release into the environment a regulated article.

R. "Plant" means any living stage or form of any member of the plant kingdom and parts thereof, including seeds, rhizomes, bulbs and corms, grafts, leaves, roots, scions and others that may be used for propagation.

S. "Plant pest" means any form of plant or animal life, or any pathogenic agent, injurious or potentially injurious to plants or plant products.

T. "Plant product" means any product derived from plants in their natural state or in processed form and are capable of harboring plant pests.

U. "Plant Quarantine Officer" means any person so appointed or designated by the Director of BPI.

V. "Person" means any natural person or juridical entity such as a corporation or cooperative.

W. "Pest-protected plant" means any plant that is made pest resistant through the use of any of the techniques of modern biotechnology.

X. "Port of entry" means a port open to both foreign and domestic trade. It includes principal ports and subports of entry.

Y. "Propagation" means the introduction, or delivery for introduction, into commerce of a regulated article for regeneration into plants or plant products for consumption by humans or animals.

Z. "Public Hearing" means the face-to-face meeting with relevant stakeholders to inform them of, and give them the opportunity to submit their comments on, any application for field testing of a regulated article which may pose significant risks to human health and the environment. The procedure for public hearing shall be as described in Section 8-H of this Order.

AA. "Public Consultation" means the process of informing relevant stakeholders of, and giving them the opportunity to submit their comments on, any application for field testing, propagation or importation for food or feed, or for processing, of a regulated article. The procedure for public consultation shall be as described in Sections 8-G, 10-E and 12-D of this Order.

BB. "Regulated article" means any of the organisms listed in Section 2-A, but excludes those delisted in accordance with Section 14.

CC. "Release into the environment" means the field testing, propagation, or direct use as food or feed, or for processing, of a regulated article.

DD. "SPS" means sanitary and phytosanitary measures, or such measures established to protect human, animal and plant life or health within the country's territory from risks from: (i) entry, establishment or spread of pests, diseases, organisms, animals, products or products thereof; and (ii) additives, contaminants, toxins or disease-causing organisms in foods, beverages or feed stuffs.

EE. "STRP" means the Scientific and Technical Review Panel created by BPI as an advisory body, composed of at least three (3) reputable and independent scientists who shall not be employees of the Department and who have the relevant professional background necessary to evaluate the potential risks of the proposed activity to human health and the environment based on

available scientific and technical information.

FF. "Transformation event" means the introduction into a plant of genetic material that has been manipulated *in vitro.*

GG. "Vector or vector agent" means any organism or molecular vehicle used to transfer genetic material from the donor organism to the host organism.

Terms used in the singular form shall be construed as the plural, and vice versa, as appropriate.

Section 2
Coverage

A. Scope. – This Order covers the importation or release into the environment of:

1. Any plant which has been altered or produced through the use of modern biotechnology if the donor organism, host organism, or vector or vector agent belongs to any of the genera or taxa classified by BPI as meeting the definition of plant pest or is a medium for the introduction of noxious weeds; or

2. Any plant or plant product altered or produced through the use of modern biotechnology which may pose significant risks to human health and the environment based on available scientific and technical information.

B. Exceptions. – This Order shall not apply to the contained use of a regulated article, which is within the regulatory supervision of NCBP.

Section 3
Risk Assessment

A. Principles of Risk Assessment.- No regulated article shall be allowed to be imported or released into the environment without the conduct of a risk assessment performed in accordance with this Order. The following principles shall be followed when performing a risk assessment to determine whether a regulated article poses significant risks to human health and the environment:

1. The risk assessment shall be carried out in a scientifically sound and transparent manner based on available scientific and technical information. The expert advice of, and guidelines developed by, relevant international organizations and regulatory authorities of countries with significant experience in the regulatory supervision of the regulated article shall be taken into account in the conduct of risk assessment.

2. Lack of scientific knowledge or scientific consensus shall not be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

3. The identified characteristics of a regulated article and its use which have the

potential to pose significant risks to human health and the environment shall be compared to those presented by the non-modified organism from which it is derived and its use under the same conditions.

4. Risk assessment shall be carried out case-by-case and on the basis of transformation event. The required information may vary in nature and level of detail from case to case depending on the regulated article concerned, its intended use and the receiving environment.

5. If new information on the regulated article and its effects on human health and the environment becomes available, the risk assessment shall be readdressed to determine whether the risk has changed or whether there is a need to amend the risk management strategies accordingly.

B. Risk Assessment Guidelines. – The conduct of the risk assessment shall be in accordance with the policies and guidelines on risk assessment issued by NCBP.

Section 4
Responsible Officer

A. Obligations of the Responsible Officer. – Any applicant for the importation or release into the environment of a regulated article shall appoint a responsible officer who shall ensure that all appropriate measures are taken to prevent significant risks to human health and the environment arising from the importation or release into the environment of the regulated article. In particular, the responsible officer shall:

1. Ensure that the applicant complies with all the requirements set forth in this Order and the conditions specified in the relevant permit; and

2. Where required in this Order, create an IBC and provide it with resources necessary to enable the IBC to evaluate and monitor properly activities involving a regulated article to ensure safe and responsible use by employees and agents of the applicant.

B. Qualifications. – The responsible officer shall be a resident of the Philippines and the highest-ranking officer of the applicant.

C. Communications with BPI. – All communications of the applicant to BPI shall be signed by the responsible officer or his duly authorized representative. The responsible officer may execute a power of attorney designating any employee of the applicant as his representative for purposes of communicating with BPI on matters relating to this Order: *Provided*, That the designation of a representative shall not excuse the responsible officer from performing the obligations listed in Section 4-A. BPI may disregard any communication from the applicant that does not contain the signature of the responsible officer or his duly authorized representative.

D. Application. – An application for a permit under this Order shall:

1. indicate the name and position title of the responsible officer and, where applicable, the name and position of his duly authorized representative;

2. be signed by the responsible officer or his duly authorized representative;

3. contain the following certification:

> *"The undersigned certifies that based on his/her personal knowledge and/or authentic documents: (i) all the information in the application are true and correct; and (ii) the application contains all information and views on which to base a decision and includes relevant data and information known to the applicant which are unfavorable to the application."*

4. be made under oath before a notary public.

E. Application File. – BPI shall open an application file for every application given due course in accordance with this Order. The application for permit, supporting documents, STRP reports, written comments submitted by other government agencies and the public, and any and all documents relating to the application shall form part of the application file. Each application file shall be assigned an identification number for reference purposes.

F. SPS Regulations. – The importation of a regulated article for whatever purpose shall be subject to the relevant SPS regulations.

PART II
APPROVAL PROCESS FOR IMPORTATION OF REGULATED ARTICLES FOR CONTAINED USE

Section 5
Policy on Importation for Contained Use

No regulated article intended for contained use shall be allowed importation or be removed from the port of entry unless duly authorized by BPI upon the endorsement of NCBP.

Section 6
Requirements for Importation for Contained Use

A. Application to Import for Contained Use – Any applicant who desires to import a regulated article for contained use shall submit the following:

1. Application Form. – Three (3) copies of the *Application to Import for Contained Use* (Annex "A") to the Director of BPI. The application shall contain the following information:

a. Names, addresses, telephone numbers, fax numbers and electronic mail addresses of:

i. The applicant;

ii. The responsible officer; and
iii. Where applicable, the duly authorized representative of the responsible officer; and
iv. The persons or entities who developed and supplied the regulated article.

b. All scientific, common, and trade names, and all designations necessary to identify the donor organism; host organism; vector or vector agent; constituents of the regulated article; and the regulated article;

c. Quantity of the regulated article to be imported and the proposed schedule and number of importations;

d. Where appropriate, a detailed description of any biological material (e.g., culture medium or host material) accompanying the regulated article during movement;

e. A detailed description of the means of movement (e.g., mail, common carrier) and by whom;

f. A detailed description of the physical containment facility and, if any, the intermediate destinations;

g. A statement that the regulated article is to be imported solely and exclusively for use in research and development under contained conditions; and

h. Any other information or data which the Director of BPI may find necessary or desirable to prevent any significant risks to human health and the environment during the importation and movement of the regulated article.

2. NCBP Letter of Endorsement. – The *Application to Import for Contained Use* shall be accompanied by a letter of endorsement from NCBP stating:

a. that NCBP has conducted a scientific and technical review of the proposal for contained use and finds the proposed activity as not posing any significant risks to human health and the environment;

b. that the physical containment facility in which the proposed activity will be performed has been found to be suitable for the purpose;

c. that NCBP endorses the importation of the regulated article for contained use; and

d. the conditions NCBP imposed upon the importation, movement, storage and use of the regulated article, if any.

B. Acceptance of Application. – Within five (5) days from receipt of the application, BPI shall

examine the application to determine if it is sufficient in form and substance and inform the applicant accordingly. If the application is sufficient in form and substance, BPI shall inform the applicant that the application has been accepted and given due course. However, if the application is incomplete or not in the proper format, BPI shall so inform the applicant. The applicant shall be given a grace period of sixty (60) days within which to correct the defect in the application. If the applicant fails to correct the defect within the grace period, the application shall be deemed denied but without prejudice to the right of the applicant to resubmit the same after the defect is corrected: *Provided,* That any application submitted after the grace period shall be treated as a new application.

C. Permit to Import for Contained Use. – Within fifteen (15) days from acceptance of the application, the Director of BPI shall approve the application if he finds that based on the application file, the importation of the regulated article for the use intended poses no significant risks to human health and the environment; otherwise, he shall deny the application. In calculating the fifteen-day period, the period of time during which BPI is awaiting further information it has requested from the applicant shall be excluded.

Upon approval of the application, a *Permit to Import for Contained Use* shall be issued in quadruplicate. The original shall be given to the applicant for presentation to the Plant Quarantine Officer at the port of entry; the duplicate shall be furnished to the Collector of Customs at the port of entry; the triplicate shall be transmitted to NCBP; and the quadruplicate shall be filed with the application. The *Permit to Import for Contained Use* shall be valid for a period of two (2) years from date of issuance, unless sooner revoked for any of the reasons set forth in Section 6-F.

D. Permit Conditions. – The permittee shall comply with the following conditions:

1. The regulated article shall be imported solely and exclusively for use in research and development under contained conditions;

2. The regulated article shall be maintained and disposed of in a manner as to prevent any significant risks to human health and the environment;

3. All packing materials, shipping containers, and any other materials accompanying the regulated article shall be treated or disposed of in such a manner as to prevent any significant risks to human health and the environment;

4. The regulated article shall be maintained only in the physical containment facility or intermediate destinations specified in the permit;

5. A Plant Quarantine Officer shall be allowed access during regular business hours to the physical containment facility or intermediate destinations where the regulated article is located and to any records relating to the importation of the regulated article;

6. Where possible, the regulated article shall be identified with a label showing the permit number, name of the regulated article and the date of importation;

7. The regulated article shall be subject to the application of measures, including final

disposal, which the Director of BPI determines to be necessary or desirable, to prevent the accidental or unauthorized release of the regulated article;

8. The permittee shall notify the Director of BPI, within the time periods and in the manner specified below, in case of any of the following occurrences:

    a. verbally immediately upon discovery, or in writing within twenty four (24) hours, in the event of any accidental or unauthorized release of the regulated article or new information becomes available indicating that the regulated article could pose significant risks to human health and the environment; and

    b. in writing as soon as possible, but not to exceed three (3) working days, if the regulated article or associated host organism is found to have characteristics substantially different from those listed in the application for a permit, or suffers from any unusual occurrence (e.g., excessive mortality or morbidity, unanticipated effect on non-target organisms);

9. In the event new information becomes available indicating that the regulated article could pose significant risks to human health and the environment, the applicant shall on its own immediately take measures necessary to protect human health and the environment;

10. The permittee shall import the regulated article only at the port of entry designated in the permit; and

11. Such other conditions as BPI may deem necessary or desirable to prevent any significant risks to human health and the environment.

E. Identification of Regulated Articles for Importation. – The documentation accompanying the regulated article shall indicate that it is or may contain a genetically modified organism.

F. Revocation of Permit. – A permit may be revoked and further permits refused for the importation of a regulated article for contained use for any of the following grounds:

1. Revocation by NCBP of its Letter of Endorsement;

2. Provision of false information in the *Application to Import for Contained Use;*

3. Misdeclaration of shipment;

4. Violation of relevant SPS or biosafety rules and regulations or of any conditions imposed in the *Permit to Import for Contained Use*;

5. Refusal to allow the inspection of the physical containment facility or intermediate destination of the regulated article; or

6. New technical information becomes available to BPI indicating that the regulated article, if allowed for its intended use, will result in significant risks to human health

and the environment.

PART III
APPROVAL PROCESS FOR FIELD TESTING OF REGULATED ARTICLES

Section 7
Policy on Field Testing

No regulated article shall be released into the environment for field testing unless: (i) a *Permit to Field Test* has been secured from the BPI; and (ii) the regulated article has been tested under contained conditions in the Philippines. The containment of a regulated article shall be reduced and the scale of release increased only if based on the risk assessment of the contained use the field testing of the regulated article will pose no significant risks to human health and the environment.

Section 8
Requirements for Field Testing

A. Application for Field Testing. – Any applicant who desires to field test a regulated article shall submit the following:

1. Application Form. – Three (3) copies of the *Application to Field Test* (Annex "B") to the Director of BPI. The application shall contain the following information:

    a. Names, addresses, telephone numbers, fax numbers and electronic mail addresses of:

        i. The applicant;
        ii. The responsible officer;
        iii. Where applicable, the duly authorized representative of the responsible officer;
        iv. The persons or entities who developed and supplied the regulated article; and
        v. All members of the IBC.

    b. The signatures of all members of the IBC and the vote of each one on the conduct of the proposed field testing. If a member did not sign the application, the reason for such failure or refusal to sign;

    c. All scientific, common, and trade names, and all designations necessary to identify the donor organism; host organism; vector or vector agent;

constituents of the regulated article; and regulated article;

d. A detailed description of the molecular biology of the systems (e.g., donor-host-vector) that are or will be used to produce the regulated article;

e. A detailed description of the anticipated or actual expression of the altered genetic material in the regulated article and how that expression differs from the expression in the non-modified parental organism;

f. Data and other information on the genetic stability of the introduced gene material;

g. Where appropriate, a detailed description of any biological material (e.g., culture medium or host material) accompanying the regulated article during movement;

h. A detailed description of the means of movement (e.g., mail, common carrier) and by whom;

i. A detailed description of the proposed experimental or production designs;

j. A detailed description of the field testing sites;

k. A detailed description of the proposed procedures, processes and safeguards which will be used to prevent escape and dissemination of the regulated article from the intended field testing site(s);

l. A detailed description of the proposed method of final disposition of the regulated article;

m. Any information known to the applicant that indicates that the regulated article may pose a greater risk to human health and the environment than the unmodified host organism; and

n. Any other information or data which the Director of BPI may find necessary or desirable to prevent any significant risks to human health and the environment during the field testing of the regulated article.

2. Supporting Documents. – The application shall be accompanied by the following documents:

a. Certification from NCBP that the regulated article has undergone satisfactory testing under contained conditions in the Philippines;

b. A technical dossier consisting of scientific literature, unpublished studies or test data, or such other scientific materials relied upon by the applicant to show that, for the use it is intended, the regulated article will not pose any significant risks to human health and the environment;

c. Copy of the proposed *Public Information Sheet for Field Testing* (Annex "C").

B. Required Additional Information and Documents for Importation of Regulated Article. – In addition to the information required under Section 8-A, an applicant who shall import a regulated article for field testing shall provide the following information in the application:

1. Country where the donor organism, host organism, vector or vector agent, and regulated article were collected, developed and produced;

2. Quantity of the regulated article to be imported and the proposed schedule and number of importations;

3. Where applicable, a detailed description of all intermediate destinations;

4. A detailed description of the processes, procedures and safeguards used in the country of origin to prevent contamination, unintentional release and dissemination in the production of the donor organism; host organism; vector or vector agent; constituent of each regulated article which is a product; and regulated article;

5. A detailed description of the potential risks of the importation and movement of the regulated article and risk management measures which the applicant undertakes to implement; and

and submit to BPI: (i) a certification from country of origin that the regulated article to be imported is of the same transformation event as that which has undergone satisfactory testing under contained conditions in the Philippines; and (ii) a notification from the exporter or country of origin in accordance with existing international agreements on the transboundary movement of genetically modified organisms.

C. Multiple Field Testing Sites. – The field testing of a regulated article regardless of the number of field test sites may be contained in a single application: *Provided, however,* That each field test site shall be evaluated separately and independently by BPI.

D. Risk Assessment by IBC. – The IBC shall evaluate the field testing proposal using the policies and guidelines on risk assessment formulated by NCBP. The IBC shall determine if the data obtained under contained conditions provide sufficient basis to authorize the field testing of the regulated article. In making the determination, the IBC shall ensure that field testing does not pose any significant risks to human health and the environment. The IBC may, in its discretion, require the proponent to perform additional experiments under contained conditions before acting on the field testing proposal. The IBC shall either endorse the field testing proposal to BPI or reject it for failing the scientific risk assessment.

E. Endorsement of Proposal by IBC. – The approval by a majority of the IBC members, including at least one community representative, shall be required before any *Application to Field Test* may be endorsed by the IBC for approval by BPI.

F. Acceptance of Application. – Within five (5) days from receipt of the application, BPI shall

examine it to determine if it is sufficient in form and substance. No application shall be accepted by BPI unless it has the endorsement of the IBC. If the application complies with the format and contains all the required information, the Director of BPI shall so inform the applicant and immediately forward copies of the application to the NCBP and the STRP. The STRP shall evaluate the application, particularly the risk assessment and risk management strategies of the applicant and submit its report to BPI within thirty (30) days from its receipt of a copy of the application.

However, if the application is incomplete or not in the proper format, BPI shall so inform the applicant. The applicant shall be given a grace period of sixty (60) days within which to correct the defect in the application. If the applicant fails to correct the defect within the grace period, the application shall be deemed denied but without prejudice to the right of the applicant to resubmit the same after the defect is corrected: *Provided*, That any application submitted after the grace period shall be treated as a new application.

G. Public Consultation – The applicant, acting through its IBC, shall notify and invite comments on the field testing proposal from the barangay and city/municipal governments with jurisdiction over the field test sites. The IBC shall post for three (3) consecutive weeks copies of the *Public Information Sheet for Field Testing* approved by the BPI in at least three (3) conspicuous places in each of the concerned barangay and city/municipal halls. The *Public Information Sheet for Field Testing* shall, among others, invite interested parties to send their comments on the proposed field testing to BPI within a period of thirty (30) days from the date of posting. It shall be in a language understood in the community. During the comment period, any interested person may submit to BPI written comments regarding the application. The applicant shall submit proof of posting in the form of certifications from the concerned barangay captains and city/municipal mayors or an affidavit stating the dates and places of posting duly executed by the responsible officer or his duly authorized representative.

H. Public Hearings. – If based on the report of the STRP, the proposed release may pose significant risks to human health and the environment, the Director of BPI shall cause the IBC to conduct public hearings within the vicinity of the proposed field test sites within thirty (30) days from the date the applicant was furnished by BPI a copy of the STRP report.

I. Permit to Field Test. – Within one hundred twenty (120) days from acceptance of the application and upon consultation with the NCBP, the Director of BPI shall approve the application if he finds that based on the application file the field testing of the regulated article poses no significant risks to human health and the environment; otherwise, he shall deny the application. In calculating the one hundred twenty-day period, the period of time during which BPI is awaiting further information it has requested from the applicant or is carrying out public hearings in accordance with Section 8-H shall be excluded.

Upon approval of the application, a *Permit to Field Test* shall be issued in quintuplicate. The original shall be given to the applicant; the duplicate shall be sent to the Regional Director of the Department with jurisdiction over the site of planned release; the triplicate shall be transmitted to NCBP; the quadruplicate to the Collector of Customs at the port of entry (if the regulated article is to be imported and no conditional permit to import was granted previously); and the quintuplicate shall be filed with the application. A *Permit to Field Test* shall be issued for every approved field test site. It is valid for a period of two (2) years from date of issuance, unless sooner revoked for any of the reasons set forth in Section 8-P. It may be extended for such

period as may be necessary to complete the field testing begun during the two-year period.

J. Permit Conditions. – The permittee shall comply with the following conditions:

1. The regulated article shall be maintained and disposed of in a manner as to prevent any significant risks to human health and the environment;

2. All packing materials, shipping containers, and any other materials accompanying the regulated article shall be treated or disposed of in such a manner as to prevent any significant risks to human health and the environment;

3. The regulated article shall be kept separate from other organisms, except as specifically allowed in the permit;

4. The regulated article shall be maintained only at the field test sites specified in the permit;

5. The regulated article shall be identified with a label showing the permit number, name of the regulated article and, where applicable, the date of importation;

6. The regulated article shall be subject to the application of measures determined by the Director of BPI to prevent the accidental or unauthorized release of the regulated article;

7. The regulated article shall be subject to the application of remedial measures, including disposal, determined by the Director of BPI to be necessary to prevent any significant risks to human health and the environment;

8. The permittee shall notify the Director of BPI, within the time periods and in the manner specified below, in case of any of the following occurrences:

    a. verbally immediately upon discovery, or in writing within twenty four (24) hours, in the event of any accidental or unauthorized release of the regulated article or new information becomes available indicating that the regulated article could pose significant risks to human health and the environment; and

    b. in writing as soon as possible, but not to exceed three (3) working days, if the regulated article or associated host organism is found to have characteristics substantially different from those listed in the application for a permit, or suffers from any unusual occurrence (e.g., excessive mortality or morbidity, unanticipated effect on non-target organisms);

9. In the event new information becomes available indicating that the regulated article may pose significant risks to human health and the environment, the applicant shall on its own report to BPI and immediately take measures necessary to protect human health and the environment;

10. Where the regulated article for field testing is to be imported, the permit shall

contain the following additional conditions:

a. The permittee shall import the regulated article only at the port of entry designated in the permit;

b. The regulated article shall be imported solely and exclusively for use in field testing; and

c. All packing materials, shipping containers, and any other materials accompanying the regulated article shall be treated or disposed of in such a manner as to prevent any significant risks to human health and the environment.

4. Such other conditions as BPI may deem necessary or desirable to prevent any significant risks to human health and the environment.

K. Conditional Permit to Import. – BPI may allow the conditional importation of a regulated article intended for field testing while the *Application to Field Test* is pending: *Provided*, That: (i) the regulated article shall be stored in a contained facility which NCBP has inspected and determined to be adequate in preventing its escape and dissemination; (ii) the cost of storing and safeguarding the regulated article shall be for the account of the applicant; (iii) in no case shall BPI or any of its officers or employees be responsible to the applicant for the loss of or damage to the regulated article; (iv) the applicant shall destroy the regulated article in strict accordance with the instructions of BPI if the *Application to Field Test* is denied; and (v) the conditional permit shall not in any way be interpreted as a commitment by BPI to approve the *Application to Field Test.*

L. Identification of Imported Regulated Article. – Where the regulated article is imported, the documentation accompanying the regulated article shall indicate that it is or may contain a genetically modified organism.

M. Approval Registry for Field Testing. – BPI shall establish and maintain a registry of regulated articles that have been approved for field testing.

N. Supervision by BPI. – The field testing of any regulated article shall be subject to the control and supervision of BPI. A Plant Quarantine Officer and his duly authorized representatives may inspect at any time the site where the regulated article is field tested.

O. Submission of Report. – Within ninety (90) days from the completion of the field testing, the applicant shall submit to BPI two (2) copies of the detailed terminal report on the results thereof. The report shall be in the format prescribed by BPI and state, among others, whether the objectives of the field testing were achieved; a detailed description of potential risks to human health and the environment observed during the conduct of the field testing; the steps taken by the applicant to mitigate them; and the final disposition of the regulated article. The duplicate copy shall be transmitted by BPI to NCBP for its reference and file.

P. Revocation of Permit to Field Test. – A *Permit to Field Test* may be revoked for any of the following grounds:

1. Provision of false information in the *Application to Field Test;*

2. Violation of SPS or biosafety rules and regulations or of any conditions specified in the permit;

3. Failure to allow the inspection of the field testing site;

4. Receipt by BPI of new information that the field testing of the regulated article poses significant risks to human health and the environment;

5. Where the regulated article was imported, misdeclaration of shipment; or

6. Such other grounds as BPI may deem reasonable to prevent significant risks to human health and the environment.

PART IV
APPROVAL PROCESS FOR PROPAGATION OF REGULATED ARTICLES

Section 9
Policy on Release for Propagation

No regulated article shall be released for propagation unless: (i) a *Permit for Propagation* has been secured from BPI; (ii) it can be shown that based on field testing conducted in the Philippines, the regulated article will not pose any significant risks to the environment; (iii) food and/or feed safety studies show that the regulated article will not pose any significant risks to human and animal health; and (iv) if the regulated article is a pest-protected plant, its transformation event has been duly registered with the FPA.

Section 10
Requirements for Release for Propagation

A. Application for Propagation. – Any applicant who desires to release for propagation a regulated article which is not listed in the Approval Registry for Propagation shall submit the following:

1. Application Form. – Five (5) copies of the *Application for Propagation* (Annex "D") to the Director of BPI. The application shall contain the following information:

   a. Names, addresses, telephone numbers, fax numbers and electronic mail addresses of:

      i. The applicant;
      ii. The responsible officer; and
      iii. Where applicable, the duly authorized representative of the responsible officer.

   b. All scientific, common, and trade names, and all designations necessary to identify the donor organism; host organism; vector or vector agent; constituents of the regulated article; and regulated article;

c. Identification number of the field testing application file;

d. Any information known to the applicant that indicates that the regulated article may pose a greater risk to human health and the environment than the unmodified host organism; and

e. Any other information or data which the Director of BPI may find necessary or desirable to prevent any significant risks to human health and the environment during the propagation of the regulated article.

2. Supporting Documents. – The application shall be accompanied by the following:

a. Certification from BPI that the regulated article has undergone satisfactory field testing in the Philippines;

b. A technical dossier consisting of scientific literature, unpublished studies or data from tests performed, or such other scientific materials relied upon by the applicant to show that the release for propagation of the regulated article will not result in any significant risks to human health and the environment;

c. Copy of the proposed *Public Information Sheet for Propagation* (Annex "E").

B. Required Additional Information and Documents for Importation of Regulated Article. – In addition to the information required under Section 10-A, an applicant who plans to import the regulated article for propagation shall provide the following information in the *Application for Propagation*:

1. Country of origin;

2. Quantity of the regulated article to be imported and the proposed schedule and number of importations;

3. Where applicable, a detailed description of all intermediate destinations;

4. A detailed description of the terms and conditions, if any, under which the regulated article has been allowed for propagation by the regulatory authorities in the country of origin; and

and submit to BPI: (i) a certification from country of origin that the regulated article to be imported is of the same transformation event as that which has undergone satisfactory field testing in the Philippines; and (ii) a notification from the exporter or country of origin in accordance with existing international agreements on the transboundary movement of genetically modified organisms.

C. Acceptance of Application. – Within five (5) days from receipt of the application, BPI shall examine it to determine if it is sufficient in form and substance. If the application complies with the format and contains all the required information, the Director of BPI shall immediately

forward a copy of the application to the STRP. The STRP shall evaluate the application, particularly the risk assessment and risk management strategies of the applicant, and submit its report to BPI within thirty (30) days from its receipt of the application.

However, if the application is incomplete or not in the proper format, BPI shall so inform the applicant. The applicant shall be given a grace period of sixty (60) days within which to correct the defect in the application. If the applicant fails to correct the defect within the grace period, the application shall be deemed denied but without prejudice to the right of the applicant to resubmit the same after the defect is corrected: *Provided*, That any application submitted after the grace period shall be treated as a new application.

D. Referral to Other Agencies. – BPI shall furnish the following agencies with a copy of the application, and each shall have thirty (30) days from receipt of the application from BPI to submit their respective comments:

1. BAFPS (in all instances), for determination of compliance with food safety standards;

2. FPA (if the regulated article is a pest-protected plant), for determination if applicant is duly licensed as a pesticide handler in accordance with P.D. No. 1144 and if tolerance levels and good agricultural practices have been established for registration of the transformation event; and

3. BAI (if the regulated article is intended for use as feed or for processing into feed), for determination of compliance with feed safety standards.

E. Public Consultation. – Within fifteen days from receipt of notice that its application has been given due course, the applicant shall cause to be published in two (2) newspapers of general circulation a copy of the *Public Information Sheet for Propagation* approved by BPI. The *Public Information Sheet for Propagation* shall, among others, invite interested parties to send their comments on the proposed release for propagation to BPI within a period of thirty (30) days from the date of publication. During the comment period, any interested person may submit to BPI written comments regarding the application and these shall become part of the application file. The applicant shall submit to the Director of BPI proof of publication within fifteen (15) days from the date of publication.

F. Permit for Propagation. – Within ninety (90) days from acceptance of the application, the Director of BPI shall approve the application if he finds that based on the application file the release for propagation of the regulated article poses no significant risks to human health and the environment; otherwise, he shall deny the application. In calculating the ninety-day period, the period of time during which BPI is awaiting further information it has requested from the applicant shall not be included.

Upon approval of the application, a *Permit for Propagation* shall be issued in quadruplicate. The original shall be given to the applicant; the duplicate to NCBP; the triplicate to the Collector of Customs at the port of entry (if the regulated article is to be imported); and the quadruplicate to be filed with the application. The *Permit for Propagation* shall be valid for a period of not more than five (5) years, unless sooner revoked for any of the reasons set forth in Section 10-K. It may be renewed for successive five-year periods upon showing by the applicant that the continued

propagation of the regulated article does not pose any significant risks to human health and the environment.

G. Permit Conditions. – The permittee shall comply with the following conditions and such other conditions which BPI shall state in the *Permit for Propagation:*

1. The permittee shall submit to BPI monitoring reports on the performance characteristics of the regulated article in accordance with the monitoring reporting requirements specified in the permit;

2. The permittee shall notify the Director of BPI, within the time periods and in the manner specified below, in case of any of the following occurrences:

    a. verbally immediately upon discovery, or in writing within twenty four (24) hours, in the event that new information becomes available indicating that the regulated article can pose significant risks to human health and the environment; and

    a. in writing as soon as possible, but not to exceed three (3) working days, if the regulated article or associated host organism is found to have characteristics substantially different from those listed in the application, or suffers from any unusual occurrence (e.g., excessive mortality or morbidity, unanticipated effect on non-target organisms);

3. Where the regulated article for propagation is to be imported, the permittee shall import the regulated article only at the port of entry designated in the permit;

4. In the event new information becomes available indicating that the regulated article could pose significant risks to human health and the environment, the applicant shall on its own immediately take measures necessary to protect human health and the environment.

H. Compliance with Other Agency Regulations. – The *Permit for Propagation* shall not excuse the applicant from complying with the relevant regulations of other government agencies.

I. Identification of Imported Regulated Article. – Where the regulated article is imported, the documentation accompanying the regulated article shall indicate that it is or may contain a genetically modified organism.

J. Approval Registry for Propagation. – BPI shall establish and maintain a registry of regulated articles that have been approved for propagation.

K. Revocation of Permit for Propagation. – A *Permit for Propagation* may be revoked for any of the following grounds:

1. Provision of false information in the *Application for Propagation;*

2. Violation of SPS or biosafety rules and regulations or of any conditions imposed in the permit;

3. Where the regulated article was imported, misdeclaration of shipment;

3. New technical information becomes available to BPI indicating that the propagation of the regulated article could pose significant risks to human health and the environment; or

5. Such other grounds as BPI may deem reasonable to protect human health and the environment.

PART V
APPROVAL PROCESS FOR IMPORTATION OF REGULATED ARTICLES FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING

Section 11
Policy on Importation for Direct Use as Food or Feed, or for Processing

No regulated article shall be allowed importation for direct use as food or feed, or for processing, unless: (i) the importation has been duly authorized by BPI; (ii) the regulated article has been authorized for commercial distribution as food or feed, as the case may be, in the country of origin; and (iii) regardless of the intended use, the regulated article poses no significant risks to human *and* animal health.

Section 12
Requirements for Importation for Direct Use as Food or Feed or for Processing

A. Application to Import for Direct Use as Food or Feed or for Processing. – Any applicant who desires to import for direct use as food or feed, or for processing, a regulated article not listed in the Approval Registry for Direct Use shall submit the following:

1. Application Form. – Three (3) copies of the *Application to Import for Direct Use* (Annex "F") to the Director of BPI. The application shall contain the following information:

    a. Names, addresses, telephone numbers, fax numbers and electronic mail addresses of:

        i. The applicant;
        ii. The responsible officer; and
        iii. Where applicable, the duly authorized representative of the responsible officer.

    b. All scientific, common, and trade names, and all designations necessary to

identify the donor organism; host organism; vector or vector agent; constituents of the regulated article; and regulated article;

c. Country of origin;

d. Any information known to the applicant that indicates that the regulated article may pose a greater risk to human health and the environment than the unmodified host organism;

e. A statement that the regulated article is to be imported solely and exclusively for direct use as food or feed, or for processing into food or feed, and not for field testing or propagation;

f. In case the regulated article can regenerate if accidentally introduced into the Philippine environment, a detailed description of the proposed procedures, processes and safeguards which the applicant will use to prevent the escape and dissemination of the regulated article; and

g. Any information or data which the Director of BPI may find necessary or desirable to prevent any significant risks to human health and the environment.

2. Supporting Documents. – The application shall be accompanied by the following

a. Notification from the exporter or country of origin in accordance with existing international agreements on the transboundary movement of genetically modified organisms; and

b. Proposed *Public Information Sheet for Direct Use* (Annex "G").

To facilitate review of the application, the applicant may submit documents to show that the regulated article is allowed for commercial distribution as food or feed by the regulatory authorities in the country of origin; and poses no significant risks to human and animal health. If the regulated article is intended for use as feed or for processing into feed, the applicant may submit documents to show that the regulatory authorities in the country of origin have likewise determined that the regulated article poses no significant risks to human health.

B. Acceptance of Application. – Within five (5) days from receipt of the *Application to Import for Direct Use*, BPI shall examine it to determine if it is sufficient in form and substance. If the application complies with the format and contains all the required information, the Director of BPI shall so inform the applicant and forward a copy of the application to the STRP. The STRP shall evaluate the application, particularly the risk assessment studies conducted and actions taken by relevant regulatory authorities in the country of origin, and submit its report to BPI within thirty (30) days from its receipt of the application.

However, if the application is incomplete or not in the proper format, BPI shall so inform the applicant. The applicant shall be given a grace period of sixty (60) days within which to correct the defect in the application. If the applicant fails to correct the defect within the grace period,

the application shall be deemed denied but without prejudice to the right of the applicant to resubmit the same after the defect is corrected: *Provided*, That any application submitted after the grace period shall be treated as a new application.

C. Referral to Other Agencies. – BPI shall furnish the following with a copy of the application for their comments:

1. BAFPS, if the regulated article is a raw agricultural commodity intended for direct use as food or processing into food; and

2. BAI, if the regulated article is intended for direct use as feed or for processing into feed.

BAFPS and BAI shall have thirty (30) days from receipt of the application to submit their comments to BPI.

D. Public Consultation. – Within fifteen (15) days from receipt of notice that its application has been given due course, the applicant shall cause to be published in two (2) newspapers of general circulation a copy of the *Public Information Sheet for Direct Use* approved by BPI. The *Public Information Sheet for Direct Use* shall, among others, invite interested parties to send their comments on the proposed importation for direct use as food or feed, or for processing, to BPI within a period of thirty (30) days from the date of publication. During the comment period, any interested person may submit to BPI written comments regarding the application and these shall become part of the application file. The applicant shall submit to the Director of BPI proof of publication within fifteen (15) days from the date of publication.

E. Permit to Import for Direct Use. – Within sixty (60) days from acceptance of the application, the Director of BPI shall approve the application if he finds that based on the application file the importation for direct use as food or feed, or for processing, of the regulated article poses no significant risks to human health and the environment; otherwise, he shall deny the application. In calculating the sixty-day period, the period of time during which BPI is awaiting further information it has requested from the applicant or from the regulatory authorities in the country of origin shall not be included.

Upon approval of the application, a *Permit to Import for Direct Use* shall be issued in quadruplicate. The original shall be given to the applicant for presentation to the Plant Quarantine Officer at the port of entry; the duplicate shall be sent to BAFPS or BAI, as appropriate; the triplicate to the Collector of Customs; and the quadruplicate shall be filed with the application. The *Permit to Import for Direct Use* shall be valid for a period of five (5) years from date of issuance, unless sooner revoked for any of the reasons set forth in Section 12-I. It may be renewed for successive five-year periods upon showing by the applicant that the continued importation of the regulated article as food or feed, or for processing, does not pose any significant risks to human health and the environment.

The *Permit to Import for Direct Use* shall not relieve the applicant of its obligation to secure permits or licenses required by BAI, BAFPS and other government agencies.

F. Permit Conditions. – The permittee shall comply with the following conditions:

1. The regulated article shall be imported solely and exclusively for direct use as food or feed, or for processing into food or feed, and not for field testing or propagation;

2. The regulated article shall be maintained and disposed of in a manner as to prevent any significant risks to human health and the environment;

3. All packing materials, shipping containers, and any other materials accompanying the regulated article shall be treated or disposed of in such a manner as to prevent any significant risks to human health and the environment;

4. A Plant Quarantine Officer and his duly authorized representatives shall be allowed access during regular business hours to the facility where the regulated article is located and to any records relating to the importation of the regulated article;

5. Where possible, the regulated article shall be identified with a label showing the permit number, name of the regulated article and the date of importation;

3. The regulated article shall be subject to the application of measures, including final disposal, which the Director of BPI determines to be necessary or desirable to prevent the accidental or unauthorized release of the regulated article;

4. The permittee shall notify the Director of BPI, within the time periods and in the manner specified below, in case of any of the following occurrences:

    a. verbally immediately upon discovery, or in writing within twenty four (24) hours, in the event of any accidental or unauthorized release of the regulated article or new information becomes available indicating that the regulated article could pose significant risks to human health and the environment; and

    b. in writing as soon as possible, but not to exceed three (3) working days, if the regulated article or associated host organism is found to have characteristics substantially different from those listed in the application for a permit, or suffers from any unusual occurrence (e.g., excessive mortality or morbidity, unanticipated effect on non-target organisms);

5. In the event new information becomes available indicating that the regulated article could pose significant risks to human health and the environment, the applicant shall on its own report to BPI and immediately take measures necessary to protect human health and the environment;

6. The permittee shall import the regulated article only at the port of entry designated in the permit; and

7. Such other conditions as BPI may deem necessary or desirable to prevent any significant risks to human health and the environment.

G. Identification of Regulated Articles for Importation. – The documentation accompanying the regulated article shall indicate that it is or may contain a genetically modified organism.

H. Approval Registry for Direct Use. – BPI shall establish and maintain a registry of regulated articles that have been approved for importation for direct use as food or feed, or for processing. No permit shall be required for the importation of regulated articles for such use: *Provided, That* within fifteen (15) days from arrival of every shipment of the regulated article, the importer shall notify BPI of such fact and stating the serial number of the permit, name of carrier, date of arrival, country of origin, name of shipper, name and address of the importer, and quantity of the regulated article imported.

I. Revocation of Permit to Import for Direct Use. – A *Permit to Import for Direct Use* may be revoked for any of the following grounds:

1. Provision of false information in the *Application to Import for Direct Use;*
2. Misdeclaration of shipment;
3. Violation of relevant SPS and biosafety rules and regulations or of any conditions imposed in the *Permit to Import for Direct Use*;
4. Refusal to allow the inspection of the physical containment facility or intermediate destination of the regulated article;
5. The legal authority to commercially distribute the regulated article in the country of origin has been suspended or revoked; or
6. New technical information becomes available to BPI indicating that the regulated article, if allowed for its intended use, will result in significant risks to human health and the environment.

J. Notice of Arrival of Shipments. – Within fifteen (15) days from arrival of every shipment of the regulated article, the permittee shall notify BPI of such fact and stating the serial number of the permit, name of carrier, date of arrival, country of origin, name of shipper, name and address of the importer, and quantity of the regulated article imported.

PART VI
DELISTING OF REGULATED ARTICLE

Section 13
Ground for Delisting

If based on the nature of a regulated article and its use, the regulated article will not pose any significant risks to human health and the environment, BPI may remove it from the coverage of this Order.

Section 14
Requirements for Delisting

A. Petition for Delisting. – Any person may file with BPI a verified petition to exclude a regulated article from the coverage of this Order. The petition, which shall be in two (2) copies, shall contain the following:

1. Name and address of the petitioner;

2. Name of regulated article that is subject of the petition;

3. Factual grounds why this Order should not apply to the regulated article;

4. Any information known to the petitioner which would be unfavorable to his petition. If the petitioner is not aware of any unfavorable information, he should state in the petition: "Unfavorable Information: NONE.".

The petition shall be accompanied by copies of published scientific literature relied upon by the petitioner.

B. Publication of the Petition. – Within five (5) days from receipt of the petition, BPI shall inform the petitioner if the petition satisfies the requirements of Section 14-A and order the petitioner to have the petition published in two (2) newspapers of general circulation with a notice soliciting comments thereon from the public. The notice shall invite interested parties to send their comments on the petition for delisting to BPI within a period of sixty (60) days from the date of publication. During the comment period, any interested person may submit to BPI written comments regarding the petition and these shall become part of the petition file. The petitioner shall submit to the Director of BPI proof of publication within fifteen (15) days from the date of publication.

C. STRP Report. – Upon granting due course to the petition, the Director of BPI shall likewise furnish a copy to the STRP. The STRP shall evaluate the petition taking into account the nature and use of the regulated article and the scientific consensus, if any, on the effect of its release on human health and the environment, and submit its report to BPI within thirty (30) days from its receipt of a copy of the application.

D. Decision. – Within one hundred twenty (120) days from receipt of the certificate evidencing publication of the petition in accordance with Section 14-B and taking into account the report of the STRP, the Director of BPI shall resolve the petition and inform the petitioner in writing of his decision. The Director of BPI shall, based on the petition file, either: (i) approve the petition, in which case the Director of BPI shall declare the regulated article as no longer covered by this Order; (ii) deny the petition; or (iii) require the petitioner to submit additional scientific literature or experimental data .

PART VII
MISCELLANEOUS PROVISIONS

Section 15
Confidential Business Information

A. If there are portions of the applications mentioned in this Order which contain trade secrets or confidential business information, each page of the application containing such information shall be marked "Commercial-in-Confidence" (CIC) by the applicant. In addition, portions of the application which are deemed "CIC" shall be so designated. The applicant shall also submit one (1) copy of the application with all the CIC deleted, but marked with "CIC deleted" on each page where the CIC was deleted. If an application does not contain any CIC, then the first page of all copies submitted to BPI shall be marked "No CIC".

B. In no case, however, shall the following information be considered CIC:

1. Name and address of the applicant;

2. Description of the regulated article;

3. Description of the intended destination (including all intermediate and final destinations), uses, and distribution of the regulated article;

4. Summary of the risk assessment of the effects of the regulated article on the environment and human health;

5. Where appropriate, description of the proposed procedures, processes and safeguards which will be used by the applicant to prevent escape and dissemination of the regulated article at each of the intended destinations;

6. Description of the methods and plans for emergency response in case of accidental release of the regulated article into the environment; and

7. Description of the proposed method of final disposition of the regulated article.

C. BPI shall inform the applicant if the information the latter identified as CIC does not qualify for such treatment and shall provide it an opportunity for consultation and review of its decision prior to disclosure to any third party.

D. An applicant may refer to data or results from applications previously submitted by other applicants: *Provided*, that (i) the information, data or results are not CIC, or (ii) if the otherwise, the previous applicants have given their consent in writing to the use of their confidential information, data or results.

Section 16
Outside Experts and Accreditation of Laboratories

In the implementation of this Order, including without limitation the evaluation of risk assessment studies and risk management measures, the BPI may coordinate, seek the services of, and consult with international or governmental agencies and public or private research institutes or laboratories, educational establishments and individuals or entities with expertise relevant to biosafety.

Section 17
Fees

With the prior approval of the Secretary of the Department, the Director of BPI may impose fees in such amount as may be necessary to cover the costs of evaluating applications and petitions and monitoring compliance with permit conditions.

Section 18
Appeal

Any person whose permit has been revoked or has been denied a permit or whose petition for delisting has been denied by the Director of BPI, may appeal the decision in writing to the Secretary of the Department within fifteen (15) days after receiving the written notification of the revocation or denial. The appeal shall state all the facts and reasons upon which the appellant bases his appeal. The Secretary of the Department shall grant or deny the appeal in writing within sixty (60) days from receipt of the appeal.

Section 19
Transition Period

There shall be a transition period of until June 30, 2003, during which time:

1. *Applications to Field Test* shall be filed with and processed by the NCBP in accordance with its Guidelines on Planned Release of Genetically Manipulated Organisms (GMOs) and Potentially Harmful Exotic Species (PHES): *Provided,* That the conduct of the field testing shall be subject to the control and supervision of BPI.

2. No permit shall be required to import for direct use as food or feed, or for processing, a regulated article that has been approved for commercial distribution as food or feed by the regulatory authorities in the country of origin: *Provided,* That in case the regulated article is intended for use as feed or for processing into feed, importation shall be allowed only if the regulatory authorities in the country of origin have likewise determined that the regulated article poses no significant risks to human health. During the transition period, BPI shall create an *Ad Hoc* STRP composed of scientists from relevant disciplines to review available scientific risk assessment data and information on regulated articles likely to be imported into the Philippines as food or feed, or for processing. If in the determination of the *Ad Hoc* STRP, a regulated article poses no significant risks to human health and the environment, BPI shall cause its registration in the approval registry under Section 12-H; otherwise, it shall immediately ban its importation and advise the public accordingly.

Section 20
Repealing Clause

All existing rules and regulations inconsistent with this Order are hereby modified, revoked or repealed accordingly.

Section 21
Separability

The provisions of this Order are hereby declared to be separable. In the event that one or more of its provisions are held to be invalid, the validity of the other provisions shall not be affected thereby.

Section 22
Effectivity

Subject to the transition period provided under Section 19, this Order shall take effect thirty (30) days after its publication in a national newspaper of general circulation.

L E O N A R D O Q . M O N T E M A Y O R
Secretary